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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,299 | 11/28/2000 | Alice M Bennett | 124-809 | 8818 |

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EXAMINER

SCHEINER, LAURIE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,299

Applicant(s)

BENNETT, A.

Examiner

Laurie A. Scheiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

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Claim 18 and SEQ ID NO:3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in their response of November 3, 2003.

The traversal is on the ground(s) that claim 18 (Group II) includes all of the details of the subject matter of Group I (claims 1-17). Thus, it follows that the claim of Group II includes the same special technical feature as the subject matter set forth by the claims of Group I. This is not found persuasive because applicant's argument is flawed. That is, the vaccines of the respective groups differ from each other in their final structure. That the vaccine of Group II contains some of the structural components of the vaccine of Group I is irrelevant since the sum of the parts of the respective vaccines differ. Moreover, a multivalent vaccine may include bacterial antigens, as well as viral antigens which differ from the instant VEE virus or variants. To make illustrative analogies, "an isolated benzene compound" is not encompassed within "an isolated naphthalene compound", even though the structure of benzene is found within the structure of naphthalene. Similarly, a portion of a nucleic acid sequence is a chemical compound which is structurally different from the full length nucleic acid sequence.

With respect to SEQ ID NO:3, applicant is concerned that the "waiver" by the Commissioner is itself waived and the Office is requiring restriction of a single nucleotide sequence per application.

The examiner contends that the number of sequences contained in the commercial data bases against which claimed sequences are searched have relatively recently expanded geometrically. In short, the search results for a single sequence can be lengthy; and a

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pragmatic approach has therefor been adopted. Thus, applicant's experience does in fact comport with recent practice of allowing for just a single sequence search per application.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

The invention appears to require a novel construct. Since TC-83 appears to be essential to the invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed construct's sequences are not fully disclosed, nor have all the sequences required for its construction been shown to be publicly known and freely available. The enablement requirements of 35 USC 112 may be satisfied by a deposit of TC-83. Accordingly, it is deemed that a deposit of the construct of the claim should have been made in accordance with 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney or record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of

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compliance by an affidavit or declaration, or by a statement by an attorney or record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Claims 2-13 and 15-17 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are improperly drafted due to the recitation of "according to any one of the preceding claims" since claim numbers and claim order may be changed during prosecution.

Thus, a latter claim at the time of the application may subsequently become a preceding claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1-17 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bennett et al. (Viral Immunology, Volume 11, Number 3, pp. 109-117, 1998).

Bennett et al. appears to be the literature equivalent of the instant 371 application of PCT/GB99/01387. Thus, no difference is seen between that which is claimed and the teachings of the reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al. (Journal of General Virology (1988) 69, 3005-3013) in view of Davison et al. (Journal of Molecular Biology (1989) 210, 749-769).

Kinney et al. teaches that the 7.5K vaccinia promoter functions to express Venezuelan Equine Encephalitis (VEE) viral genes inserted into a vaccinia vector.

Davison et al. teach synthetic promoters efficient at increasing gene expression can be constructed which correspond to the 7.5K vaccinia promoter with mutations within the critical region AAAAGTaGAAAaTA.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kinney et al. and Davison et al. such that the vaccinia virus vector

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encodes an immunologically protective attenuated form of VEE with increased VEE viral gene expression under the control of the 7.5K vaccinia promoter.

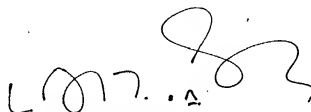
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.



Laurie Scheiner/LAS
March 14, 2004



LAURIE SCHEINER
PRIMARY EXAMINER